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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,793	04/09/2004	Luc J. Farmer	VPI/03-170 US	9337
27916	7590	01/08/2008		
VERTEX PHARMACEUTICALS INC. 130 WAVERLY STREET CAMBRIDGE, MA 02139-4242			EXAMINER KOSACK, JOSEPH R	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 01/08/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/821,793		FARMER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Joseph Kosack		1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 40-53 is/are pending in the application.
- 4a) Of the above claim(s) 46-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 40-53 are pending in the instant application.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 2, 2007 has been entered.

#### ***Previous Specification Objections***

The disclosure was objected to for containing an indefinite definition of the compounds in the action mailed January 18, 2006. The specification has been corrected and the objection is withdrawn.

#### ***Previous Claim Rejections - 35 USC § 112***

Claims 1-7, 15-29, 35-38, and 41-45 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's amendments have removed the indefinite subject matter, and the rejection is withdrawn.

#### ***Previous Claim Rejections - 35 USC § 103***

Claims 1-7, 15-29, 35-38, and 40-45 were rejected in the action mailed January 18, 2006 under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al. (*J. Org. Chem.* 1997, 765-770) in view of Babine et al. (WO 02/18369).

Applicant's amendments have removed the obvious subject matter, and the rejection is withdrawn.

### ***Previous Double Patenting Rejections***

Claims 1-5, 15-29, 35-38 and 40-45 were provisionally rejected in the action mailed January 18, 2006 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-16, 21-29, and 34 of copending Application No. 10/614,432, now published as US 20040077600 A1, in view of Patani et al. (*Chem. Rev.* 1996, 3147-3176).

Applicant has chosen not to address this rejection, as it is still provisional. The application has not been patented and the rejection remains provisional. The rejections are maintained for claims 40-45. The rejections have been withdrawn from claims 1, 5, and 15-29 in that those claims have been cancelled. Even though this is a provisional rejection, it cannot be removed since the conflicting application has an earlier filing date.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

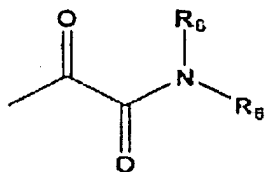
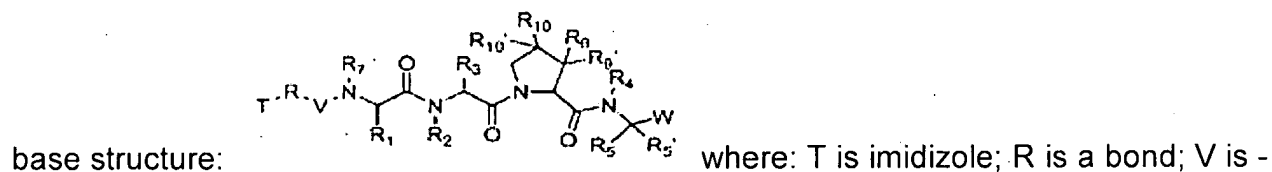
USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

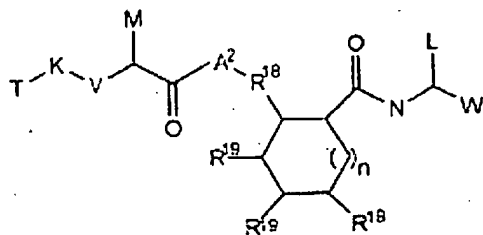
Claims 40-45 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-16, 21-29, and 34 of copending Application No. 10/614,432, now published as US 20040077600 A1, in view of Patani et al. (*Chem. Rev.* 1996, 3147-3176).

The instant application cites two specific compounds which fall generally into the

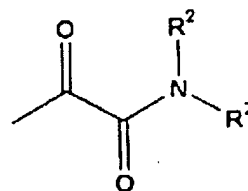


C(O)-; W is ; R<sub>9</sub>, R<sub>10</sub>, R<sub>10'</sub> are X-Y-Z where X & Y are bonds and Z is hydrogen; R<sub>9'</sub> is X-Y-Z where X & Y are bonds and Z is C<sub>1-12</sub> aliphatic, C<sub>3-10</sub> cycloalkyl, or C<sub>3-10</sub> cycloalkyl- C<sub>1-12</sub> aliphatic, substituted as defined; and all other substituents are as defined.

'432 teaches a compound with a base structure:



where n is 0; W is



; L is

alkyl, alkenyl, or alkynyl optionally substituted with halogen, sulfhydryl or hydroxyl;  $R^{18}$  is a bond,  $A^2$  is  $-NR^{11}-CH(M)-C(O)-$ ; V is  $NR^{11}$ , K is C(O), T is imidazole,  $R^{19}$  can be H or alkyl substituted with aryl, and all other substituents are as defined.

'432 does not teach a 5-membered ring with N bound to  $R^{18}$  instead of C to form an amide linkage instead of a ketone linkage.

Patani et al. teach the bioisosteric replacement of an CH group with N by Grimm's Hydride Displacement Law. See page 3148, column 2, lines 12-31.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the claimed invention was made to take the compound of '432 and modify the the ring CH connected to  $R^{18}$  using the bioisosteric replacement of Patani et al. with a reasonable expectation of success. The motivation to make the claimed compound derives from the expectation that structurally similar starting materials are generally expected to have similar properties and have similar utilities. *In re Gyurik*, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979).

This is a provisional obviousness-type double patenting rejection.

### **Conclusion**

Claims 40-45 are rejected.


Application/Control Number:  
10/821,793  
Art Unit: 1626

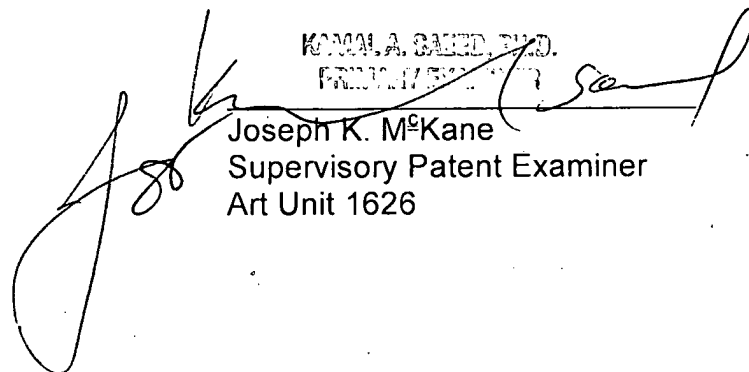
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 6:30 A.M. until 4:00 P.M. The examiner has every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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